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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,620	12/05/2001	Makoto Ozeki	1422-0507P	8140

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,620

Applicant(s)

OZEKI ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 10, 12-14 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-9, 11, 16-18 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
HUMERA N SHEIKH
PRIMARY EXAMINER

TC-1600

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 11/01/06.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Claims 1-14 and 16-28 are pending in this action. The rejection of claims 1-3, 10, 12-14 and 19 has been affirmed (see BPAI decision of 9/21/06). Claims 1-3, 10, 12-14 and 19 have been *withdrawn* and are not subjected to further review in view of the decision by BPAI dated 09/21/06. Claims 4-9, 11, 16-18 and 20-28 are now rejected over Ueda *et al.* (U.S. Patent No. 6,831,103 B1).

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-9, 11, 16-18 and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (U.S. Patent No. 6,831,103 B1).

The instant invention is drawn to a method for promoting sleep in an individual having sleep disorders, comprising administering an effective sleep-promoting amount of theanine to the individual having sleep disorders.

The instant invention is also drawn to a method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid.

The instant invention is also drawn to a method of promoting sleep in a human having a sleep disorder, comprising: administering to a human an effective amount of theanine to moderate or ameliorate a sleep disorder selected from the group consisting of insomnia, vigilance in middle of sleep, vigilance in early morning and disturbance of restful sleep.

Ueda *et al.* ('103) teach a theanine-containing composition, which can be used for a food composition, pharmaceutical composition and the like, for suppressing and ameliorating various symptoms accompanying diminished homeostasis, such as sleep disorders, obesity, anxiogenic symptoms, premenstrual syndrome, sensitivity to cold, menopausal disorders and autonomic

imbalance. The invention also includes a mineral composition, in which peculiar taste is reduced that comprises theanine and a mineral (see Abstract); (column 1, lines 13-22); (col. 1, line 66 – col. 2, line 17). Methods of treating an individual in need of suppressing or ameliorating one or more symptoms accompanying diminished homeostasis is also disclosed (see Claims 1-18 at columns 19-22).

According to Ueda *et al.*, the composition of the invention comprising theanine has suppressive and ameliorating effect on various diseases, including amelioration of sleep disorders (col. 3, lines 50-59). Additional symptoms that can be treated include insomnia (col. 5, lines 54-65).

Ueda *et al.* teach that any of L-theanine, D-theanine and DL-theanine are usable, among which the L-form is preferred in the present invention, because it is approved as a food additive and it is economically utilizable (col. 3, lines 13-16). In addition, the theanine used may be of any forms, such as purified products, crudely purified products, extracts and the like (col. 3, lines 16-19). The theanine contained in the mineral composition may also be any of L-form, D-form and DL-form. Among them L-form is preferable because its improvement of the effect of the metal taste is high (col. 8, lines 47-51).

The amount of administration of the theanine for sufficiently exhibiting the amelioration effect for sleep disorders is preferably from 0.2 to 200 mg/kg* day (col. 6, lines 3-6). Theanine content in the composition may be adjusted and is preferably from 0.00025 to 100% by weight (col. 4, lines 15-21). Theanine can be formulated in dry foods, supplements, liquid foods, such as soft drinks, mineral water, luxury beverages and alcoholic beverages (col. 6, lines 17-32). When the theanine-containing composition is used for a pharmaceutical composition, its forms

include any one of solutions, suspensions, powders, molded solids and the like and can be provided as capsules, tablets, powders, granules, drinks and the like (col. 7, lines 18-29); (col. 8, lines 30-46).

The composition may further comprise a mineral (col. 3, lines 21-22). Suitable minerals disclosed include iron, magnesium, copper, zinc, selenium, calcium, potassium, manganese, chromium, iodine, molybdenum, nickel and vanadium or salts thereof. The mineral may be constituted by a single metal element or a plurality of metal elements (col. 3, lines 22-37); (col. 7, lines 42-51).

In addition, the theanine can be used in combination with other ingredients. Other ingredients taught include herbs, extracts, vitamins and dietary sweeteners (col. 3, lines 38-49).

Example 6, Table 3, at columns 11-12 demonstrates theanine-containing candies using L-theanine, granulated sugar, malt syrup, flavor (lemon), tartaric acid and water.

Figure 5 demonstrates a graph showing sleeping time for theanine-administered group, non-applying group, and non-administered group, respectively (col. 2, lines 38-40).

Example 12 at column 18, lines 50-67 demonstrate administration of theanine, whereby sleeping time was measured. The results confirmed that the sleep disorders in menopause was suppressed by the administration of the theanine composition.

It is the position of the Examiner that the instant invention would be deemed *prima facie* obvious, given the explicit teachings of Ueda *et al.* Ueda *et al.* vividly teach methods for ameliorating or suppressing conditions of sleep disorders, insomnia and the like, by administration of a theanine composition, that includes minerals, sugars, acids (tartaric) and flavors. The prior art clearly recognizes and teaches formulations and methods for suppressing

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sleep disorders in an individual, whereby the formulations are comprised of similar components as claimed by Applicant and used for the same field of endeavor to treat similar problems (*i.e.*, sleep disorders). Thus, based on the explicit teachings of Ueda *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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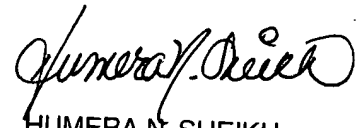
system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

November 6, 2006


HUMERA N SHEIKH
PRIMARY EXAMINER

TC-1600

hns